

§ 106-140.1. Registration of producers of prescription drugs and devices.

(a) On or before December 31 of each year, every person doing business in North Carolina and operating as a wholesaler, manufacturer, outsourcing facility, or repackager, as those terms are defined in subsection (j) of this section, shall register with the Commissioner his name and business location(s) in North Carolina. If said person has no business locations in North Carolina, he shall register his name and location of his corporate offices.

(b) Every person, upon first operating as a wholesaler, manufacturer, outsourcing facility, or repackager in North Carolina shall immediately register with the Commissioner his name, place of business, and such establishment. If said person has no business locations in North Carolina, he shall register his name and location of his corporate offices.

(c) Every person duly registered in accordance with subsections (a) and (b) of this section shall register with the Commissioner any additional establishment that he owns or operates in the State of North Carolina prior to doing business as a manufacturer, wholesaler, outsourcing facility, or repackager.

(d) The Commissioner may assign a registration number to any person or any establishment registered in accordance with this section.

(e) The Commissioner shall make available for inspection to any person so requesting any registration filed pursuant to this section.

(f) The following classes of people are exempt from the registration requirements of this section:

- (1) Pharmacists as defined in G.S. 90-85.3(q) holding a valid permit as defined in G.S. 90-85.3(m).
- (2) Practitioners licensed or registered by law to prescribe or administer drugs and who manufacture, prepare, compound, or process drugs or devices solely for use in the course of their professional practice.
- (3) Persons who manufacture, prepare, compound, or process drugs solely for use in research, teaching, or chemical analysis and not for sale.
- (4) Other classes of persons the Commissioner may by rule exempt from the application of this section upon a finding that registration by these classes of persons in accordance with this section is not necessary for the protection of the public health.
- (5) Wholesale distributors of prescription drugs licensed under G.S. 106-145.3.

(g) Every establishment in the State of North Carolina registered with the Commissioner pursuant to this section shall be subject to inspection pursuant to G.S. 106-140.

(h) The Commissioner shall adopt rules to implement the registration requirements of this section. These rules shall provide for an annual registration fee of one thousand dollars (\$1,000) for companies operating as manufacturers, outsourcing facilities, or repackagers and seven hundred dollars (\$700.00) for companies operating as wholesalers. The Department of Agriculture and Consumer Services shall use these funds for the implementation of the North Carolina Food, Drug and Cosmetic Act.

(i) For the purposes of this act, name means the name of the partnership if a partnership and the name of the corporation if a corporation.

(j) As used in this section:

- (1) The term "manufacturer" means a person who prepares, derives, or produces a prescription drug. Pharmacists are specifically excluded from this definition if they are acting in the course of their professional practice as defined in Chapter 90 and rules adopted pursuant to it.
- (1a) The term "outsourcing facility" means a manufacturer at a single geographic location or address that is engaged in the compounding of sterile drugs, has elected to register as an outsourcing facility with the Food and Drug

Administration, and complies with the requirements as provided in 21 U.S.C. § 353b. Exemptions provided by 21 U.S.C. § 353b(a) with respect to labeling, new drug registration, and distribution supply chain requirements shall also apply to compounded drugs distributed in North Carolina by an outsourcing facility.

- (2) The term "prescription drug" means a drug that under federal law is required, prior to being dispensed or delivered, to be labeled with the following statement: "Caution: Federal law prohibits dispensing without a prescription."
- (3) The term "repackager" means a person who repacks, relabels, or manipulates a prescription drug which was in a unit packaged and sealed by a manufacturer. Pharmacists are specifically exempted from this definition if they are acting in the course of their professional practice as defined in Chapter 90 and rules adopted pursuant to it.
- (4) The term "wholesaler" means a person acting as a jobber, wholesale merchant, salvager, or broker, or agent thereof, who sells or distributes for resale a prescription drug. Pharmacists are specifically exempted from this definition if they are acting in the course of their professional practice as defined in Chapter 90 and rules adopted pursuant to it. (1987, c. 737, s. 2; 1989, c. 226, s. 2; 1989 (Reg. Sess., 1990), c. 1024, s. 20; 1991, c. 699, ss. 3, 4; 1997-261, s. 109; 2015-241, s. 13.4(a); 2015-263, s. 32; 2015-268, s. 5.1.)